UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,724	06/20/2006	**Jun Keun Chang**	CHANG222	6592

1444 7590 03/20/2009

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
KINGAN, TIMOTHY G	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
03/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,724	CHANG ET AL.	
	Examiner	Art Unit	
	TIMOTHY G. KINGAN	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/20/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 4-10 and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over A. Daridon, U.S. Patent Application Publication 2004/0229349 (herein after Daridon) in view of M.S. Goel and S.L. Diamond, Blood 100(10): 3797-3803, 2002 (herein after Goel) and S. Usami et al., Ann. Biomed. Engineering 21: 77-83, 1993.

For Claims 1, 4, 10 and 13, Daridon teaches a microfluidic apparatus for manipulation of particles such as cells or beads (micro particle is a cell or bead), the mechanisms for manipulation comprising controlled movement or positioning in a channel, allowing particles to be sorted as single particles or mixed groups (abstract)

(positioned in a focusing channel). Daridon teaches an embodiment in which focusing occurs in a channel with an "acceleration" region ([0505], Figs, 31 and 32, **1042**), such region comprising a nozzle with left and right walls (fixed walls of solid material), the walls being inclined relative to a horizontal. Further, Daridon teaches the cross sectional view of the region **1042** is assymetric, in the horizontal, along a line passing along the length (Fig. 32). Daridon does not specifically teach a decrease in the cross sectional area of the nozzle in the vertical direction from the entrance to the exit or a decrease in height of the nozzle of the channel from entrance to exit. However, Daridon does teach that passages may have any suitable width and height and may follow any suitable path, including linear and curvilinear [0137].

Examiner notes that Fig. 32 discloses that the nozzle or acceleration region 1042 narrows from entrance to exit, such element comprising a de facto teaching of a decrease in cross sectional area in the horizontal direction. Further, Goel teaches that adhesion of cells decreases with increasing shear stress on such cells (abstract), and Usami teaches the shear stress τ_w in a flow channel varies inversely with channel height and width (p. 81, ¶ 1, equation 23). It would have been obvious to one of ordinary skill in the art at the time of invention to use a nozzle, wider and higher at its entrance with respect to its exit, by inclination of opposing walls, in order to provide for an increased shear in the nozzle, with the expectation of reduced adhesion of cells in a sorting mechanism, according to the teachings of Goel and Usami, based on acceleration of particles with the narrowing and/or effective curvature of the channel.

Daridon further teaches detection by spectroscopic methods comprising detection of electromagnetic radiation in a number of forms [0238]. While Daridon does not specifically teach photographing images from the detection region or an analysis means for such images, it would have been obvious to one of ordinary skill in the art to include such capability in a detection system in order to provide for automated analysis such as determination of image intensities, including the steps of defining edges through analysis of intensities and storage of such information for display.

For Claims 5 and 14, Daridon teaches the positioning of particles in a microfluidic system (channel) may be determined by the presence of additional flow streams within the channel, providing laminar-flow based mechanisms [0192] (right and left walls are fluid walls), the relative distributions of inlet flow steams maintained after unification in laminar flow [0192].

For Claims 6 and 15, Daridon teaches that channels have surfaces that form walls [0137]. Further, a number of embodiments, in the teaching of Daridon, comprise walls which are parallel with each other (e.g., Figs. 2A-4). It would have been obvious to one of ordinary skill in the art to use parallel and fixed upper and lower walls of the channel in order to minimize the possibility of turbulence and to provide for uniformity in flow rate, particularly in a detection zone.

For Claims 7 and 16, Daridon does not specifically teach a decrease in the height of the nozzle from the entrance to the exit or an asymmetric formation in the inclination surfaces. However, Daridon does teach that passages may have any suitable width and height and may follow any suitable path, including linear and curvilinear [0137]. It is

evident from Fig. 32 that the nozzle or acceleration region 1042 narrows from entrance to exit, such element comprising a *de facto* teaching of a decrease in cross sectional area. Further, Goel teaches that adhesion of cells decreases as the shear stress increases on such cells (abstract) and Usami teaches the shear stress τ_w in a flow channel varies inversely with channel height and width (p. 81, ¶ 1, equation 23). It would have been obvious to one of ordinary skill in the art at the time of invention to use a nozzle, with inclination surfaces at the upper and lower walls forming an opening higher at its entrance with than at its exit, in order to provide for an increased shear, with the expectation of reduced adhesion of cells in a sorting mechanism, according to the teachings of Goel and Usami, based on acceleration of particles with the narrowing of the channel. Daridon, Goel and Usami do not teach upper and lower walls formed asymmetrically. However, Daridon teaches sorting mechanisms based on differential centrifugal forces experienced on particles in a curved region **1044**, creating angular velocity and radial acceleration [0505] in contributing to sorting. Such acceleration, higher on the inside of a curved region, creates an asymmetric distribution of shear force with respect to the cross section of the channel, as would an asymmetry in the inclinations of paired opposite walls, either horizontal or vertical pairs. One of ordinary skill in the art would find obvious to use physical channel configurations in order to provide asymmetric distribution of shear force across the channel with reasonable expectation that such asymmetry would reduce adhesion through differential acceleration.

For Claims 8 and 17, Daridon, Goel and Usami do not specifically teach the height of the channel with respect to the particle. However, it would have been obvious to one of ordinary skill in the art that the height of the channel not be less than the diameter of the micro particle in order to prevent such particles becoming wedged or stuck in the channel.

For Claims 9 and 18, Daridon teaches a microfluidic apparatus for manipulation of particles such as cells or beads (micro particle is a cell or bead), the mechanisms for manipulation comprising controlled movement or positioning in a channel, allowing particles to be sorted as single particles or mixed groups (abstract).

4. Claims 2-3 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daridon in view of Goel and Usami as applied to claims 1 and 10, respectively, above, and further in view of T. Kawano and T. Yamada, U.S. Patent 6,994,218 (herein after Kawano).

Daridon, Goel and Usami do not teach differences in the left and right inclination walls with respect to the entrance of the channel. Kawano teaches an apparatus for sorting cells comprising a passage with a cell alignment portion (abstract). Further, Kawano teaches a pair of guiding surfaces (inclination surfaces) at the entrance to a nozzle (col 9, lines 3-8; Fig. 4a, **19c**). The elements of applicant's claims comprising "closer to the entrance" and "diameter of the micro particle", small and/or uncertain in magnitude, are within the teaching of Kawano. It would have been obvious to one of

ordinary skill in the art to modify the modified device of Daridon to include the inclined surfaces of Kawano in order to guide the cells into the channel.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY G. KINGAN whose telephone number is (571)270-3720. The examiner can normally be reached on Monday-Friday, 8:30 A.M. to 5:00 P.M., E.S.T..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TGK

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797